

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended		
2. Request for Proposal (RFP) Number: N02-CM-01008-03	3. Issue Date: July 1, 2009	4. Set Aside: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes Part IV Section L
5. Title : Clinical Trials Monitoring Service		
6. ISSUED BY: Office of Acquisitions National Cancer Institute National Institutes of Health _____ _____ _____ _____		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 pm local time on July 31, 2009. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH SUBPARAGRAPH (c)(3) OF FAR CLAUSE 52.215-1, ENTITLED, "INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION" LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov		
11. FOR INFORMATION CALL: Erin Bain PHONE: (301) 435-3814 e-MAIL: bainerin@mail.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
		Richard L. Hartmann Contracting Officer Office of Acquisitions National Cancer Institute

RFP TABLE OF CONTENTS

PART I - THE SCHEDULE	4
SECTION A - SOLICITATION/CONTRACT FORM	1
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS	4
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT	7
SECTION D - PACKAGING, MARKING AND SHIPPING	10
SECTION E - INSPECTION AND ACCEPTANCE	10
SECTION F - DELIVERIES OR PERFORMANCE	11
SECTION G - CONTRACT ADMINISTRATION DATA	14
SECTION H - SPECIAL CONTRACT REQUIREMENTS	17
PART II - CONTRACT CLAUSES	27
PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS	35
SECTION J - LIST OF ATTACHMENTS	35
SOLICITATION ATTACHMENTS	35
TECHNICAL PROPOSAL ATTACHMENTS	35
BUSINESS PROPOSAL ATTACHMENTS	35
INFORMATIONAL ATTACHMENTS	35
PART IV - REPRESENTATIONS AND INSTRUCTIONS	37
SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	37
SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS	38
1. GENERAL INFORMATION	38
a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION	38
b. NAICS CODE AND SIZE STANDARD	42
c. TYPE OF CONTRACT AND NUMBER OF AWARDS	42
d. PERFORMANCE BASED ACQUISITION	42
e. ESTIMATE OF EFFORT	42
f. COMMITMENT OF PUBLIC FUNDS	42
g. COMMUNICATIONS PRIOR TO CONTRACT AWARD	43
h. RELEASE OF INFORMATION	43
i. REFERENCE MATERIALS	43
j. PREPARATION COSTS	43
k. SERVICE OF PROTEST	43
2. INSTRUCTIONS TO OFFERORS	44
a. GENERAL INSTRUCTIONS	44
1. Contract Type and General Clauses	44
2. Authorized Official and Submission of Proposal	44
3. Proposal Summary and Data Record (NIH-2043)	44
4. Separation of Technical and Business Proposals	44
5. Alternate Proposals	45
6. Evaluation of Proposals	45
7. Potential Award Without Discussions	45
8. Use of the Metric System of Measurement	45
9. Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)	45

10. Privacy Act - Treatment of Proposal Information.....	45
11. Selection of Offerors.....	46
12. Past Performance Information.....	47
13. Electronic and Information Technology Accessibility.....	48
14. Solicitation Provisions Incorporated by Reference.....	48
b. TECHNICAL PROPOSAL INSTRUCTIONS.....	49
1. Technical Discussions.....	49
2. Other Considerations.....	56
3. Information Security.....	56
c. BUSINESS PROPOSAL INSTRUCTIONS.....	61
1. Basic Cost/Price Information.....	61
2. Cost and Pricing Data.....	61
3. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data.....	64
4. Small Business Subcontracting Plan.....	65
5. HUBZone Small Business Concerns.....	67
6. Total Compensation Plan.....	67
7. Other Administrative Data.....	68
8. Qualifications of the Offeror.....	71
9. Subcontractors.....	71
10. Proposer's Annual Financial Report.....	72
11. Travel Costs/Travel Policy.....	72
SECTION M - EVALUATION FACTORS FOR AWARD.....	73
1. GENERAL.....	73
2. EVALUATION OF OPTIONS.....	73
3. TECHNICAL EVALUATION CRITERIA.....	73
4. PAST PERFORMANCE FACTOR.....	74
5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION.....	75

PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this project is to assist the Cancer Therapy Evaluation Program (CTEP), NCI in fulfilling its responsibilities in meeting the regulations set forth by the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) as an Independent New Drug (IND) sponsor and funding agency by monitoring NCI sponsored clinical trials.

ARTICLE B.2. ESTIMATED COST, FIXED FEE AND AWARD OPTION

a. Estimated Cost and Base Fee

1. The estimated cost of the Base Period of this contract is \$_____.
2. The fixed fee for the Base Period of this contract is \$_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.
3. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Fixed Fee (\$)
Base Period: May 1, 2010 - April 30, 2011			
Option Period: May 1, 2011 - April 30, 2012			
Optional Task A:			
Implementation Year 1			
Implementation Year 2			
Maintenance Cost \$ Per Year (Note: up to 5 years)			
Optional Task B:			
FY 2011 (5 additional audits)			
FY 2012 (5 additional audits)			
FY 2013 (5 additional audits)			
FY 2014 (5 additional audits)			
FY 2015 (5 additional audits)			
(5 additional audits)			
FY 2016 (5 additional audits)			
(5 additional audits)			
Total [Base Period and Option(s)]			

b. Award Options

1. If the Award Option(s) are earned pursuant to the AWARD OPTION QUALITY ASSURANCE SURVEILLANCE PLAN (QASP) Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Fixed Fee (\$)
Base Period (FY10)			
Award Option 1 (FY12)			
Award Option 2 (FY13)			
Award Option 3 (FY14)			
Award Option 4 (FY15)			
Award Option 5 (FY16)			
Total [Base Period and Award Option(s)]			

c. Total Estimated Contract Amount

1. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee of the Base Period is \$_____.
2. If the Government exercises its options pursuant to the OPTION PROVISION Article in SECTION H of this contract, and if the Award Options are earned pursuant to the AWARD OPTION QUALITY ASSURANCE SURVEILLANCE PLAN (QASP) Article in Section H of this contract, the Government's total estimated contract amount, represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Award Fee (\$)
Base Period (FY10)			
Option Period (FY11)			
Optional Task A			
Optional Task B			
Award Options (FY12-FY16)			
Total Base Period plus Option Period plus Optional Work plus Award Options			

3. Total funds currently available for payment and allotted to this contract are \$_____ of which \$_____ represents the estimated costs, and of which \$_____ represents the fixed fee. For further provisions on funding, see the LIMITATION of FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.
4. It is estimated that the amount currently allotted will cover performance of the contract through_____.
5. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated May 27, 2009, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.*

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) 2 hard copies of these reports will be required as follows:

- ☐ Monthly
- ☐ Quarterly
- ☐ Semi-Annually
- ☐ Annually
- ☐ Annually (with a requirement for a Draft Annual Report)
- ☒ Final - Upon final completion of the contract
- ☐ Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

2. **Task 1 Reports** - Patient Registration, Protocol Patient Data Capture and Quality Control Reviews for Phase 0, Phase 1 and Selected Phase 2 Clinical Trials

- a. **Monitors Summary (MS) Report** - a summary of the administrative conduct of studies, data submission status, protocol status, and patient accrual and basic performance indicators. The MS Report shall contain an administrative table listing for each study. The administrative table shall include institution; title of study; phase of study; protocol #; investigator; date of patient registrations; assigned dose levels; date of first course; and date of last course. The MS report shall also contain a status table listing for each study including, drug; regimen; dosing schedule; # of registered patients; # of patients with toxicity; # of patients with response; highest toxicity grade; and, category of toxicity.
- b. **Clinical Studies Summary (CSS)** - a summary of dose levels, adverse events, and incidence of toxicity. This report shall contain at least the following reports for each study: 1) Patient Summary - by study to include: patients registered; number of evaluable patients; current dose

level and dose. For each patient the following will be included: identifier, disease, sex, age, ethnic/racial origin, treatment assignment code (TAC), current dose level, number of courses treated, first cycle toxicity including grade, second and subsequent cycle toxicity grade 2 or higher, best response, date of study, and reason for removal from study. 2) Toxicity Summary - all toxicities by dose, category and grade. The total number of patients, evaluable courses and summaries per dose level should be included in the toxicity summaries. Reports shall be available for all toxicities regardless of relatedness to investigational agent(s).

- c. **Monitors Detail (MD) Report** - a detailed section display for each study to include: tabulation of registered patients on study including patient and course disposition; the date of last protocol patient test data on file for each treatment course; the percentage of missing items; and comments on investigator performance.
- d. **Clinical Studies Detail (CSD) Reports** - shall include the following types of reports: 1) Patient Detail Report - by patient contains: demographics, eligibility, TAC, course information, physician notes, prior therapies, concomitant medications; 2) Patient Summary Report - by patient contains: demographics, TAC, dose, and disease description (e.g. lesion dimensions, quantitative bone marrow involvement); 3) Toxicity Detail Report - detail of toxicities by patient by Common Terminology Criteria for Adverse Events (CTCAE) category; 4) Study Synopsis Report - brief protocol patient study summary; 5) Toxicity Cross Tabulation - incidence of toxicity by category and dose level; and, 6) Response Summary - details of patients with significant responses.
- e. **Special Ad Hoc Reports** - (approximately 35/year) shall be generated as requested by the Project Officer(s). These shall be submitted electronically with a rapid turnaround time of as little as 24 hours. All submitted data will be available via EXCEL spreadsheets or in a pre-determined format. The sample of the types of reports that may be generated are: 1) Compliance Indicators: measures of eligibility, delinquency, and lab testing; 2) Lesion Responses: listing of lesion measurements; 3) Drug Administration: per protocol patient; 4) Escalation Highlight: tabulation of courses by dose level; 5) Lab Inquiry: details of specific lab test by day for all patients; 6) Response Evaluation: lesion measurements and investigator evaluations; 7) Summary of Eligibility; eligibility statistics; 8) Severe Toxicities: details of severe (Grade 4 and 5) adverse events; 9) Activity Indicators: status, registered patients, accrual, closure date, patients still on-study, etc; 10) Summary of AEs: incidence of AEs by category and grade; 11) Prior Therapies and Concomitant Meds: listings; 12) Categorized Toxicity Tabulation: listing of toxicities; 13) Physician Notes: listing of physician and data manager comments; 14) Inferred Toxicities: adverse events inferred from lab data; and, 15) Endpoint Follow-up: occurrence of severe, related toxicities by dose level.

3. Final Report

The Final Report shall be in sufficient detail to explain comprehensively the results achieved and shall contain a summary (not to exceed 200 words) of the salient results achieved during the performance of the contract. This report shall comprehensively summarize in tabular form the results achieved for all Tasks, for example, the number of audits performed, number of co-site visits and number of patient cases reviewed, etc. The final report shall be submitted on or before the expiration day of the contract performance period.

4. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

b. Other Reports/Deliverables

1. Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Contracting Officer's Technical Representative is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
National Cancer Institute
Executive Plaza North
6130 Executive Boulevard
MSC 7436, Room 6108
Bethesda, MD 20892-7436

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from _____ through _____.
- b. If the Contractor earns any Options pursuant to the OPTION PROVISION Article in Section H of this contract and/or any Award Options pursuant to the AWARD OPTION QUALITY ASSURANCE SURVEILLANCE PLAN (QASP) Article in Section H of this contract, the period of performance will be increased as listed below:

Option/Award Option Year	Option/Award Option Period

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below:

Item	Description	SOW/ RFP Reference	Delivered To (Copies)	Due Date
1.	Monitor's Summary (MS) (Task 1)	A.15.a (SOW)	Contracting Officer's Technical Representative (1), Contracting Officer (1), Senior Investigators in IDB (9), Project Manager of Drug Development Support Contract (1)	Monthly, on or before the 10th of each month
		A.15.a (SOW)	Senior Investigator in IDB (1), Project Manager of Drug Development Support Contract (1)	Two months prior to the due date of the Annual Report to the FDA
2.	Clinical Studies Summary (CSS) (Task 1)	A.15.b (SOW)	Contracting Officer's Technical Representative (1), Senior Investigators in IDB (9), Project Manager of Drug Development Support Contract (1)	Monthly, on or before the 10th of each month
		A.15.b (SOW)	Senior Investigator in IDB (1), Project Manager of Drug Development Support Contract (1)	Two months prior to the due date of the Annual Report to the FDA
		A.15.b (SOW)	Cross referenced IND sponsor drug companies (3 copies)	Monthly, on or before the 10th of each month
3.	Monitor's Detail (MD) (Task 1)	A.15.c (SOW)	Contracting Officer's Technical Representative (1)	Two months prior to the due date of the Annual Report to the FDA

Item	Description	SOW/ RFP Reference	Delivered To (Copies)	Due Date
		A.15.c (SOW)	Senior Investigator in IDB (1), Project Manager of Drug Development Support Contractor (1)	Two months prior to the due date of the Annual Report to the FDA
		A.15.c (SOW)	Principal Investigator or institutional contact for specific protocols (3 copies)	Quarterly, first report due August 10 th
		A.15.c (SOW)	Cross referenced IND sponsor drug companies (3 copies)	Quarterly, first report due August 10 th
4.	Clinical Summary Detail (CSD) (Task 1)	A.15.d (SOW)	Contracting Officer's Technical Representative (1)	Two months prior to the due date of the Annual Report to the FDA
		A.15.d (SOW)	Senior Investigator in IDB (1), Drug Development Support Contractor (1)	Two months prior to the due date of the Annual Report to the FDA
		A.15.d (SOW)	Principal Investigator or institutional contact for specific protocols (3 copies)	Quarterly, first report due August 10 th
		A.15.d (SOW)	Cross referenced IND sponsor drug companies (3 copies)	Quarterly, first report due August 10 th
5.	Special Ad Hoc Reports (Task 1)	A.15.e (SOW)	Contracting Officer's Technical Representative (1)	Within 24 hours of Contracting Officer's Technical Representative request, as needed basis
6.	Task 2 Audit Report	C.3 (SOW)	Contracting Officer's Technical Representative (1)	Within 10 working days of the last day of the audit
7.	Task 3 Co-Site Preliminary Audit Report	D.4 (SOW)	Contracting Officer's Technical Representative (1)	Within 24 hours of the end of the audit
8.	Task 3 Co-Site Final Audit Report	D.5 (SOW)	Contracting Officer's Technical Representative (1)	Within 15 working days after the site visit
9.	Task 4 Cancer Center/Single Institution Site Visit Report (Draft)	E.5 (a-n) (SOW)	Contracting Officer's Technical Representative (2)	Within 20 working days after the completion of the audit
10.	Task 4 Cancer Center/Single Institution Site Visit Report (Final)	E.5/E.6 (SOW)	Contracting Officer's Technical Representative (1)	Within 5 working days of receiving comments from the Contracting Officer's Technical Representatives
11.	International Collaborator Reports	G.2 (SOW)	Contracting Officer's Technical Representative (1)	Within 10 working days of the international collaborator meeting
12.	Quarterly Financial Reports For Tasks I-V	A.16; C.5; D.7; E.9; G.4 (SOW)	Contracting Officer's Technical Representative (1) Contracting Officer (1)	Quarterly or at any time upon request by the Contracting Officer's Technical Representative or Contracting Officer, first report due August 10 th
13.	Final Report	C.2 (RFP)	Contracting Officer's Technical Representative (1); Contracting Officer (1)	On or before the expiration date of the contract

Item	Description	SOW/ RFP Reference	Delivered To (Copies)	Due Date
14.	Individual Subcontracting Report (ISR)	H.8 (RFP)	Contracting Officer (1)	Annually on April 30 th , October 30 th and the expiration date of the contract
15.	Summary Subcontract Report (SSR)	H.8 (RFP)	Contracting Officer (1)	Annually on October 30th
16.	Roster of Employees Requiring Suitability Investigations	H.9 (RFP)	Contracting Officer's Technical Representative (1); Contracting Officer (1)	Within 14 calendar days of the effective date of the contract
17.	Information Security Training Report	H.9 (RFP)	Contracting Officer's Technical Representative (1); Contracting Officer (1)	Include with the first Monitor's Summary Report; April 10, 2010
18.	Reporting of New and Departing Employees	H.9 (RFP)	Contracting Officer's Technical Representative (1); Contracting Officer (1)	Within 5 working days before a new employee assumes a position
19.	Contractor - Employee Non-Disclosure Agreement(s)	H.9 (RFP)	Contracting Officer's Technical Representative (1)	As deemed necessary
20.	Self Assessment Reporting	H.9 (RFP)	Contracting Officer's Technical Representative (1); Contracting Officer (1)	Annually, April 30th
21.	Information System Security Plan Reporting	H.9 (RFP)	Contracting Officer's Technical Representative (1)	August 1 , 2010
22.	Section 508 Annual Report	H.10 (RFP)	Contracting Officer's Technical Representative (1); Contracting Officer (1)	Annually, September 1 st

- b. Copies of each report shall be sent to the Contracting Officer and Contracting Officer's Technical Representative via email. In addition a hard copy shall be sent to the following address:

U.S. Mail	Hand Carry/Delivery Services
Contracting Officer	Contracting Officer
Epidemiology, Therapeutics and Sciences Branch	Epidemiology, Therapeutics and Sciences Branch
Office of Acquisitions	Office of Acquisitions
National Cancer Institute	National Cancer Institute
Executive Plaza South, Room 6001	Executive Plaza South, Room 6001
6120 EXECUTIVE BLVD MSC 7193	6120 EXECUTIVE BLVD
BETHESDA, MD 20892-7220	ROCKVILLE, MD 20852
Email: bainerin@mail.nih.gov (Contract Specialist)	

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER/CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE

The following Project Officer(s) also known as the Contracting Officer's Technical Representative will represent the Government for the purpose of this contract:

To be specified prior to award.

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

- a. The original invoice shall be submitted to the following **designated billing office**:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

- b. One copy of the invoice shall be submitted to the following **approving official**:

Contracting Officer
Office of Acquisitions
National Cancer Institute, NIH
EPS, Room 6064
6120 EXECUTIVE BLVD MSC 7193
BETHESDA, MD 20892- 7193

E-Mail: Richard.Hartmann@nih.gov

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is the National Cancer Institute .
- b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch E - ncibranchinvoices@mail.nih.gov.
- c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- e. Invoice Matching Option. This contract requires a two-way match.
- f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC-7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "Contractor's Guide for Control of Government Property," which can be found at:

http://www.hhs.gov/oamp/policies/contractors_guide_for_control_of_gov_property.pdf.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://oamp.od.nih.gov/OD/CPS/cps.asp>

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.3. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.4. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.5. PRIVACY ACT, HHSAR 352.270-11 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm>.

ARTICLE H.6. OPTION PROVISION

Unless the Government exercises its option(s) pursuant to the Option Clauses set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract.

Option A: Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. Option A requires a two (2) year integration period and up to five (5) years of maintenance. Option A may be exercised anytime during the contract period of performance. If the option is not exercised on the anniversary date of the contract, the estimated cost plus fixed fee will be prorated. If the Government exercises this option, notice must be given at least 15 days prior to the exercise of the option, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST, FIXED FEE AND AWARD OPTION Article in SECTION B of this contract.

Option B: Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. This option may be exercised in increments of five (5) audits above a base of 30-35 audits per year as part of the contract with a maximum of one (1) increment (5 total additional audits) for years 2011-2014 and two (2) increments (10 total additional audits) exercised for years 2015-2016. Option B may be exercised anytime during the contract period of performance. If the Government exercises this option, notice must be given at least 15 days prior to the exercise of the option, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST, FIXED FEE AND AWARD OPTION Article in SECTION B of this contract.

Option to Extend the term of the contract (FY 11: May 1, 2011 April- 30, 2012): Pursuant to Far Clause 52.217-9, Option to Extend the Term of the Contract set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST, FIXED FEE AND AWARD OPTION Article in SECTION B of this contract.

ARTICLE H.7. AWARD OPTION QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

a. Award Option Contract

The Contractor may earn award options as described below. If the Contracting Officer determines that the Contractor's performance merits the award option, the estimated cost plus fixed fee will be increased as set forth in the ESTIMATED COST, FIXED FEE AND AWARD OPTION Article in SECTION B of this contract.

This Contract contains Award Option(s). The Contractor is not entitled to the exercise of any Award Options solely by meeting the criteria of the Quality Assurance Surveillance Plan (QASP). The Award Option evaluation serves as a precursor to the Government exercising its unilateral rights in accordance with FAR Part 17.2. A successful Award Option evaluation precedes the Government's review and determination to exercise or not to exercise the Award Option, in accordance with FAR Part 17.2

Award Option(s) that have not been exercised may be cancelled (rather than terminated), should the need for the items or services no longer exist. No equitable adjustments to the contract price will be applicable, as the determination not to exercise the Award Option is not considered a termination for convenience. There is no guarantee the Government will continue Performance beyond the base performance period.

Award Option(s) will be exercised based on the criteria set forth below, and the final decision whether to exercise the Award Option(s) will be made annually and is at the sole discretion of the Contracting Officer. If

the Contracting Officer determines that the Award Option has been earned, and the Government's need for the items or services still exists, the estimated cost plus fixed fee will be increased as set forth in the ESTIMATED COST, FIXED FEE AND AWARD OPTION Article in SECTION B of this contract.

b. Award Option Provisions

This contract has a base performance period of 1 year, May 1, 2010 - April 30, 2011 with a 1 year optional period from May 1, 2011 - April 30, 2012. The Contractor will have the opportunity to earn 5 additional years of work, May 1, 2012 - April 30, 2017 using the evaluation process described herein. These additional years of work are called Award Options. The total duration of this contract, including all options and Award Options, shall not exceed a period of 7 years, May 1, 2010 - April 30, 2017.

A unilateral contract modification to add the Award Option will be issued when scoring meets or exceeds that set forth in the contract. The Government shall issue this modification at least 60 days prior to contract expiration. The Award Option determination and the methodology for determining the award option are unilateral decisions made solely by the Government and are not subject to dispute.

1. Quality Assurance Surveillance Plan

- a. The Contractor's performance under this contract will be observed and evaluated continuously by the Government. The Contractor Assessment Report will be used to assess Contractor performance and determine whether the Contractor will receive Award Option(s). The Contractor Assessment Report includes Performance Indicators and Standards which identify the indicators to be evaluated and the associated standards for each indicator. A copy of the "Contractor Assessment Report/Performance Indicators and Standards," dated June 9, 2009 is included as an attachment in SECTION J of this contract.
- b. The "Contractor Assessment Report/Performance Indicators and Standards" will be prepared by the Government, resulting in an overall rating which will be disseminated to the Contractor annually. The Award Option(s) earned will be determined based upon review of the Contractor's performance against the performance indicators and standards as follows:
 1. Using the 0-5 point score in the Plan, the Contractor must receive an average of 4.125 or better in the first two years of Contractor performance. In years three, four and five the Contractor must receive an average of 4.4375 or better in each year to earn the Award Options. These goals are intended to be a stretch for the Contractor, but achievable.
 2. At the conclusion of year one, the Government will prepare a summary of the "Contractor Assessment Report/Performance Indicators and Standards" which will set forth the rating for the first year of performance. This report will be used to determine if the Award Option for year three has been earned. Likewise, at the conclusion of year two, three, four and five, the Government will prepare a "Contractor Assessment Report/Performance Indicators and Standards" and a summary report for each year to determine if the Award Option for years four, five, six and seven have been earned.

The advance evaluation of performance is required to allow adequate time for recompetition of the requirement in the event that Contractor performance does not meet the Award Option requirements. If the Contractor does not earn the first Award Option, there will be no opportunity to earn subsequent Award Option(s) and the contract expiration date will remain unchanged.

3. The "Contractor Assessment Report/Performance Indicators and Standards" described herein contains rating criteria used solely to assess whether the Contractor has earned the award option(s) specified in this contract. This report differs from the Contractor Performance Report described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract, which uses a standard rating criteria established for the Federal Contractor Performance System to evaluate overall contract performance. For this reason, the Contractor's performance scores for determining authorization of the award option(s) may differ from the Contractor's performance scores for overall contract performance.

2. Changes to the Contractor Assessment Report/Performance Indicators and Standards

Unilateral changes to the Contractor Assessment Report/Performance Indicators and Standards may be made if the Contractor is provided written notification by the Contracting Officer at least 30 days before the start of the upcoming evaluation period. Changes affecting the current evaluation period must be by mutual agreement of both parties.

3. Contractor Performance Assessment

The Project Officer, and other Government personnel as appropriate, will use the "Contractor Assessment Report/Performance Indicators and Standards" and the associated performance elements and standards to score contract performance for the Award Option determination. The Contracting Officer is responsible for making the final decision on the Contractor's score and for determining whether the Contractor has earned the Award Option.

4. Contractor Performance Evaluation

The Project Officer and Contracting Officer will prepare reports required by FAR 42.15 and described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract to determine the Contractor's overall contract performance. Unless specifically identified as a rating criterion in the "Contractor Assessment Report/Performance Indicators and Standards," this evaluation report will not be used in the Award Option determination.

ARTICLE H.8. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>.

1. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30th
October 30th
Expiration Date of Contract

2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the following individuals shall be included as contacts for notification purposes at the following e-mail address:

Richard.Hartmann@nih.gov Contracting Officer
bainerin@mail.nih.gov Contract Specialist

koyr@mail.nih.gov

Procurement Technician

ARTICLE H.9. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

☐ Administrative, Management and Support Information

☐ Mission Based Information

b. Security Categories and Levels

Confidentiality Level: ☐ Low ☐ Moderate ☐ High

Integrity Level: ☐ Low ☐ Moderate ☐ High

Availability Level: ☐ Low ☐ Moderate ☐ High

Overall Level: ☐ Low ☐ **Moderate** ☐ High

c. Position Sensitivity Designations

- The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

☐ **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI)

☐ **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

☐ **Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

- The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level

of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

3. Contractor/Subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/Subcontractor employee to work under the contract.

d. Information Security Training

The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. The listing of completed training shall be included in the first Monitor's Summary Report. Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.

Contractor/Subcontractor staff shall complete the following additional training prior to performing any work under this contract:

e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
3. Departing employees:

- Provide the name, position title, and security clearance level held by or pending for the individual.
- Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

1. Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

2. Contractor-Employee Non-Disclosure Agreements

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer no later than the completion date of the period of performance.

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

ARTICLE H.10. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding \$100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

[(End of HHSAR 352.270-19(b))]

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: <http://508.hhs.gov/> under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

Schedule for Contractor Submission of Section 508 Report:

See Article F.2, Deliveries

[(End of HHSAR 352.270-19(c))]

ARTICLE H.11. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

ARTICLE H.12. CONFIDENTIALITY OF INFORMATION

The following information is covered by **HHSAR 352.224-70, Confidentiality of Information** (January 2006):

The Contractor shall ensure the confidentiality of the following data or information of the following data or information which may be made available to the Contractor in the course of the work to be performed hereunder: 1) confidential information about NCI investigators such as their registration status, address, phone numbers, FAX numbers and e-mail addresses; findings of site visits/audits and any disciplinary actions and/or sanctions; 2) proprietary information contained in Investigational New Drug Applications (INDs); Investigator Brochures; NCI approved protocol documents; proprietary data in NCI databases; data and/or clinical information submitted from investigational sites to the contractor in performance of duties related to this contract; 4) confidential information about all clinical information collected, stored or analyzed through the CTEP databases; 5) all information regarding clinical trials and related proprietary data. Any dissemination of data relating to these documents and information shall be cleared through the Contracting Officer for the purpose of identifying an inadvertent disclosure of the data or information prior to any oral or written release of information. This includes any standards reports, ad hoc queries or abstracts.

ARTICLE H.13. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. _____"

ARTICLE H.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.15. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

2. Noncommercial Supply Items Warranty**YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS**

The Contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the item documentation provided by the Contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS	
Software for remote data capture	

(End of Clause)

ARTICLE H.16. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: <http://www.usfa.fema.gov/hotel/index.htm>.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

ARTICLE I.1. General Clauses for a Cost-Reimbursement Service Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (April 2008) is added.
- b. FAR Clause **52.225-1, Buy American Act--Supplies** (June 2003) is deleted in its entirety and FAR Clause **52.225-3, Buy American Act--Trade Agreements--Israeli Trade Act** (February 2009) is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2008).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://www.oig.hhs.gov/fraud/hotline/OIG_Hotline_Poster.pdf

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (September 2007).
4. FAR Clause **52.208-9, Contractor Use of Mandatory Sources of Supply or Services** (October 2008).
5. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within 15 days...."

6. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

"(a) The Government may extend the term of this contract by written notice to the Contractor within 6 months of the expiration date of the contract; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension."

"(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 7 years."

7. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....

[] Offeror elects to waive the evaluation preference."

8. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (April 2008).

9. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

10. FAR Clause **52.224-2, Privacy Act** (April 1984).

11. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

12. FAR Clause **52.232-18, Availability of Funds** (April 1984).

13. FAR Clause **52.237-3, Continuity of Services** (January 1991).

14. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

15. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

16. FAR Clause **52.246-23, Limitation of Liability** (February 1997).

17. FAR Clause **52.248-1, Value Engineering** (February 2000).

18. FAR Clause **52.251-1, Government Supply Sources** (April 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).

c. *NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:*

The following clauses are attached and made a part of this contract:

1. **NIH (RC)-7, Procurement of Certain Equipment** (April 1984).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (April 2009).

(a) *Definitions.* As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/services/contractingopportunities/sizestandardstotics/>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that

they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it [] is, [] is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

(End of clause)

b. FAR Clause 52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees (December 2004)

(a) Definition. As used in this clause --

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at <http://www.nlr.gov>.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations,

including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	Attachment1.pdf
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp
Attachment 3:	Statement of Work	Attachment3.pdf
Attachment 4:	Government Furnished Property	Attachment4.pdf
Attachment 5:	Quality Assurance Surveillance Plan	
Attachment 6:	Contractor Assessment Report/Performance Indicators and Standards	

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 7:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 8:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Small Business Subcontracting Plan	http://www.hhs.gov/osdbu/SubcontractPlan-FY08.doc
Attachment 10:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 11:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 12:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 13:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 14:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 15:	Privacy Act System of Records	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm

Attachment No.	Title	Location
Attachment 16:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 17:	Government Property Schedule	To be determined during negotiations.
Attachment 18:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 19:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 20:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **Online Representations and Certifications Application (ORCA)** at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

which can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

(a) *Definitions. As used in this provision--*

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).*

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) Contract award.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be

necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals

in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541990.
2. The small business size standard is \$7 million.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that one award will be made from this solicitation and that the award will be made on/about May 1, 2010.

It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a one (1) year base period, May 1, 2010 - April 30, 2011 with one (1) option year period, May 1, 2011 - April 30, 2012 and five (5) award term option years from May 1, 2012 - April 30, 2017 (See Section L.2.c. Business Proposal Instructions).

d. PERFORMANCE BASED ACQUISITION

The Government intends to use a Performance Based Acquisition method in the evaluation and award of any contract resulting from this RFP.

The Performance Based contract is designed to motivate the Contractor to perform at a higher standard. Outstanding performance is rewarded through an incentive defined in the contract. The following performance incentive will be used in any contract awarded from this RFP:

Award Option(s) (AO): This contract includes one or more options extending the contract period of performance, which the Contractor may earn based upon periodic evaluations of Contractor performance. Under the Award Option(s) incentive, if the Contractor's evaluated performance meets the Award Option criteria set forth in the Quality Assurance Surveillance Plan (QASP), the Contractor earns the right to be considered for the Award Option. The QASP is included in this RFP and located in Section J, Attachments.

e. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 31,943 labor hours per year. In addition, the Government considers the total estimated effort of Option A to be 9,320 labor hours and the total estimated effort of Option B to be 3,157 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. REFERENCE MATERIALS

Additional information about this requirement is available at the following websites:

<http://ctep.info.nih.gov/reporting/>

<https://cabig.nci.nih.gov/overview/>

http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/vocabulary

<http://www.cdisc.org/standards/bridg.html>

http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr

http://integratedtrials.nci.nih.gov/ict/CTWG_report_June2005.pdf

<https://cabig.nci.nih.gov/vendor-cdms/vendor-tradename-clinical-data-management-system-cdms/?searchterm=cdms>

<https://www.ctsu.org/>

Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

j. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of Acquisitions
National Cancer Institute
EPS, Room 6064
6120 EXECUTIVE BLVD MSC 7193
BETHESDA MD 20892- 7193

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. Contract Type and General Clauses

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. **Evaluation of Proposals**

The Government will evaluate proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

7. **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

8. **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

9. **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)**

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the Government is provided. This is to advise offerors that for this project, the Government intends to assert additional copyright permissions under this contract. The scope of the Government's interest in the copyright will be determined during negotiations.

10. **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

11. Selection of Offerors

- a. The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
 1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal,

but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

12. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Three years and the last 5 contracts awarded currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as greater than \$100,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

13. Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2008)

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794D), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Provisions (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit:

1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this solicitation are identified in the Statement of Work/ Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government - i.e., after award of a contract/order, that products and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

14. Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate

information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. *Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).*
- b. *Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).*
- c. *Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*
- d. *Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*
- e. *Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).*

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a. Statement of Work

1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate. The offeror should explain the methodologies for assuring quality performance, quality control and flexibility to meet shifting priorities.

4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

5. Awareness of Project Needs: Approach to Performance of Tasks

- a. Demonstrate and describe the approach to maintaining and updating a large protocol patient data capture and quality control review system, have working knowledge of the special needs of oncologic studies as well as FDA regulations and Good Clinical Practices. Discuss experience with on-site monitoring of clinical trials. Describe the approach to protocol patient data capture including data receipt via tape, disk, and remote data entry, data processing, review and reporting, interaction with investigators (e.g. clarification of queries) and preparation of institutional reports.

Describe the approach to maintaining the confidentiality of patient records and patient identification and to achieve the objectives of harmonization of CTEP databases, particularly with emphasis on caBIG™ initiatives, including but not limited to: the common data elements established by the Cancer Data Standards Repository (caDSR), event coding using standardized dictionaries such as MEdDRA, the Enterprise Vocabulary System developed by NCI, the Biomedical Research Integrated Domain Group (BRIDG), and the Clinical Data Interchange Standards and Health Level 7 (HL7) for data transfer. Discuss the possibility for adoption of a remote data capture system (Clinical Data Management System (CDMS)) to be purchased by NCI and how CDMS could best be incorporated to meet the requirements for Task 1 of the Statement of Work.

- b. The offeror should discuss overall approaches to special problems in clinical trials monitoring and clinical research.
 - i. Discuss the approach for performing Task II: Auditing of Phase 0, Phase 1 and selected Phase 2 Clinical Trials.
 - ii. Discuss the approach for performing Task III: Co-Site Visit Monitoring of NCI Clinical Trials Cooperative Groups, Community Oncology Program (CCOP) Research Bases, Clinical Trials Support Unit (CTSU) and Selected Multi-Institutional Consortia with Quality Assurance Programs.
 - iii. Discuss the approach for performing Task IV: Auditing of Investigators Conducting Clinical Trials Sponsored by DCTD at Cancer Centers and Single Institutions. The offeror should provide a reassurance of the ability

to expand the scope of Task IV audits to include additional audits as directed by the Project Officer.

- iv. Discuss the approach to performing Task V: Quality Assurance Program Support for International Group/Institution.
- c. Demonstrate knowledge of federal regulations (including FDA regulations) and their application to clinical trials, Good Clinical Practices and International Conference on Harmonization (ICH) standards.
- d. The offeror shall maintain a backup personnel system for key personnel and key positions. Provide a detailed description of how the contract performance will be maintained during fluctuations in the personnel needs as a result of high or low levels of work, etc. Also explain in detail the plan for maintaining performance during periods of extended absences by personnel (defined as greater than 10 consecutive working days). For personnel proposed as "backup" personnel to key positions, curriculum vitae or resumes should be provided. Backups named must be thoroughly familiar with the position that they are supporting.
- e. Describe training plans (including training for backup and fill-in personnel) and plans for replacement of proposed staff through-out the course of the contract. Describe your plans for backup coverage of proposed staff when absent due to vacations, medical leave, etc., in order to assure the work scope requirements are completed in an accurate and timely fashion.
- f. Describe the organizational management plan that would support your technical transition plan for a smooth transfer of responsibilities from the incumbent contractor.

b. Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program and specifically to which tasks each employee would be assigned. Also, demonstrate which employees will be available on short notice, and under conditions of multiple and competing tasks.

Offerors should indicate the total FTEs assigned to the project and specify the FTE distribution for each task (Tasks I-V) outlined in the Statement of Work. Provide a Personnel Ranking Matrix which indicates the hierarchical line of supervisory authority, and indicate which Contractor position(s) will perform the various tasks.

Provide complete detailed resumes of the Principal Investigator, Project Manager and all other senior level personnel that indicate their educational background, and recent research experience associated with biomedical research monitoring. Include any related training or certification specifically related to the contract tasks to be conducted. State the estimated time to be spent on each Task (Tasks I-V) as well as the total time on the project.

Key personnel shall not be consultants. For proposed consultant relationships to be acceptable, the prospective Contractor shall provide signed agreements between itself and the consultant (excluding physicians who may possibly participate as outside reviewers on cancer center or single institution audits or special response reviews) clearly stating the availability for assignment and the priority of this project's needs in relation to the needs of the consultant's employer, if any, and/or other projects in which the consultant may be involved. Please note that subcontractor staff (if included) may not be proposed for

the Principal Investigator, Project Manager, Physician(s)/CRC and Head Data Manager positions.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, PROJECT MANAGER, HEAD DATA MANAGER AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

The contractor should provide a team with the following qualifications:

1. Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible. The Principal Investigator should have a M.D. or Pharm.D. degree or 8-10 years of equivalent experience in a biomedical discipline with specific expertise and experience in the field of oncology. Experience in supervising efforts similar to those to be conducted under the contract is required.

2. Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

4. Other Investigators and Additional personnel shall include the following positions:

a. Project Manager:

List the name of the Project Manager who shall be responsible for the overall day-to-day operations and management of the contract. The Project Manager is responsible for the staffing of the contract, monitoring hours and costs invoiced to the contract and authorizing purchases within the scope of the contract. The Project Manager is also responsible for the overall personnel management including the integration and oversight of all subcontractor staff and/or consultants if applicable. The Project Manager shall be an employee of the offeror and not a consultant or subcontractor. He/she must have the authority to commit company resources as needed for efficient and timely completion of work under this contract.

The Project Manager should have a M.D. or Pharm.D. degree or 6-8 years of equivalent experience in a biomedical discipline and experience in supervising efforts similar to those to be conducted under the contract. Discuss experience in directing a project with multiple tasks and the ability to shift priorities. Describe experience in managing a multi-disciplinary team of individuals whose main function is to collect, review, and process and provide quality control data for clinical trials with a primary focus on oncologic clinical trials. Describe knowledge and extensive experience in auditing clinical trials in order to provide leadership, direction and oversight to the staff on the contract. Although the responsibility for direct supervision of these personnel could be assigned to another individual on the contract, the Project Manager should demonstrate the breadth of knowledge to offer overall guidance on issues related to data collection, development of case report forms using standardized nomenclature, processing, and quality control and database systems for clinical trials. The Project Manager should keep abreast of the latest developments in the field of oncology and assist investigators with the addition of new elements to protocols and case report forms that reflect current science.

Demonstrated knowledge and experience is required in: coordination and management of multi-institutional trials, FDA regulations, Good Clinical Practices (GCP), auditing of clinical trials including performing chart reviews of patient cases, regulatory documents and conducting pharmacy inspections.

b. Physician(s)/Clinical Research Coordinator(s) (CRC)

The CRC should be a physician(s), Pharm.D.(s) or individual(s) with equivalent degree(s) with in-depth knowledge of HHS, NIH and FDA regulations, Good Clinical Practices, and the conduct of oncologic clinical trials. Describe experience in the conduct of on-site audits and in the monitoring of performance of investigators/sites involved in the conduct of investigational agent clinical trials. Discuss medical knowledge experience for reviewing patient eligibility and experience in evaluating treatment and study performance. Describe experience in the medical review of patient cases for the overall data management of clinical trials. He/she should have strong interpersonal skills to interact positively with the NCI extramural community and should have good writing skills. The Physician or CRC shall be an employee of the offeror and not a consultant or subcontractor.

c. Head Data Manager

List the name of the Head Data Manager. This individual should have a bachelor's degree in a biomedical discipline or 6-8 years of equivalent experience in a biomedical research environment. Describe knowledge and expertise in the day-to-day activities associated with coordination and management of early phase (phase 0, 1 and select phase 2) clinical trials, including methods and procedures for protocol abstraction, data collection, quality control and queries of submitted data, the status of queries and follow-up to responses to queries and on-site audit findings. Describe knowledge of FDA regulations, Good Clinical Practices, web-based clinical databases and electronic reporting systems (such as AdEERS, CDUS). Discuss supervisory authority to shift resources to accomplish data entry and analysis and oversee special projects.

Document and demonstrate experience with the following: software designed and developed for the use of patients treated on all phases of clinical trials; Web based systems, systems for database security, and systems integration utilizing multiple software arenas; and, computerized data entry, data maintenance and data retrieval, including the archiving of old data.

d. Programming and Systems Analysis Staff

The Programming Staff should have the experience to operate a computerized protocol patient data capture and quality control review system, perform updates, assure compatibility of systems with other DCTD data collection and reporting systems, perform procedures to meet changing requirements, and perform ad hoc maintenance and reporting. Describe experience with relevant database management systems and concepts; this includes: program language and design, data communications facilities, systems integration with other data management systems, micro/main frame computing equipment and a web-based informatics environment. Demonstrate experience in the following: oversee development, operations and maintenance of the protocol patient data capture and quality control review system, and the ability to analyze requirements for database structure, data collection techniques and report contents. Discuss experience in designing, testing, validating, coding and documenting large computer based systems and knowledge of database concepts, data telecommunication technologies, programming languages and methodologies and operating systems. Programming staff should be proficient in medical informatics and the use of remote data capture systems, and various items related to caBIG™ initiatives including but not limited to: the common data elements established by the Cancer Data Standards Repository (caDSR), the Enterprise Vocabulary System developed by NCI, adverse event grading and reporting systems such as CTCAE, Adverse Event Electronic Reporting System, the Medical Dictionary for Regulatory Activities (MedDRA) and standards for electronic data transfer such as, Biomedical Research Integrated Domain Group (BRIDG), Clinical Data Interchange Standards and Health Level 7 (HL7).

Describe experience in the following software applications: ORACLE, FOCUS, HTML, JAVA or other web based scripting language, and commercial Web Browsers.

e. Clinical Research Associates (CRA)

CRA's should have 4-6 years of experience in auditing and familiarity with FDA regulations and knowledge of Good Clinical Practices. Discuss staff's experience in monitoring data collection, protocol compliance,

accuracy of data, toxicity/adverse event reporting and methods of assuring investigator compliance to federal regulations. One team member should be designated to be specifically responsible for making all arrangements and scheduling audits.

f. Data Management Staff

Describe experience in data collection, process and review and use of computerized reporting systems. Data management staff review patient data for protocol compliance, assemble reports for submission to the NCI and abstract protocols for monitoring.

g. Data Management Technicians:

Describe experience in receiving, logging and distributing patient data and protocols, supporting study data, maintaining patient study files, and retrieving and updating existing patient files.

h. Administrative

Discuss secretarial and administrative support for typing audit reports, correspondence and other support type duties. He/she should have experience with word processing on PCs.

5. Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

c. Organizational Experience and Support Capabilities

Organizational experience is defined as accomplishment of work, either past or ongoing which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in the RFP.

1. The offeror should describe in detail prior experience of the organization in furnishing services similar to each area described in the Statement of Work. The proposal should include sufficient information to demonstrate the previous effectiveness of the firm in similar or related work. Include documentation with specific reference(s) to applicable contract number(s), date(s) of agreement(s) and dollar volume. This documentation should include clear and concise description of these project(s) and should indicate the project sponsor (e.g., pharmaceutical company, government contract or grant, etc.). For each of the described projects, references (including phone numbers) should be provided. The Offeror should also reference any relevant experience in collaborating with other designated contractors providing support to the Cancer Therapy Evaluation Program or any other relevant corporate experience that demonstrates the ability to work collaboratively with other stakeholders to meet a project's mission and goals.
2. Describe the relationship of the proposed working group within the offeror's organizational structure as well as how this relationship may facilitate collaboration within the organization in performance of this project. Information should be provided on how the organization will support the Principal Investigator and/or Project Manager in resolving problems or special situations.

3. If the proposal includes the use of a subcontractor, describe the supervision and management of subcontract staff. Provide information that demonstrates that the prime and subcontractor can work together in a seamless and effective manner to accomplish coordinated tasks.
4. Describe fully the proposing organization's recruitment processes and practices. Provide employee retention rates for the past five (5) years.
5. Include a statement on the priority your organization would place on this work effort as compared to other commitments now or reasonably expected during the proposed period of performance of the contract.

d. Facilities and Equipment

1. Provide detailed information regarding the facilities and equipment available for use on this project or clearly describe how they will be available at the start of the project. Specifically, provide a detailed description of computers, printers, software and computer facilities and equipment.
2. Submit a plan, including the location and security of the remote facility, for maintaining a duplicate database. The offeror must have adequate and secure facilities to house personnel, and storage space for retention of required files (approximately 2,500 linear feet of files). A floor plan should be provided.

2. Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
 - b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
 - c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
 - d. Other factors you feel are important and support your proposed research.
 - e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.
3. **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

☐ Administrative, Management and Support Information:

☒ Mission Based Information:

D.20.1 Research and Development; D.19.1 Scientific and Technical Research and Innovation

b. Security Categories and Levels

Confidentiality Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Overall Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High

c. Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each Contractor (including subcontractor) employee that the successful offeror proposes for work under the contract. For proposal preparation purposes, the following designations apply:

☐ **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

☒ **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI)

☐ **Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the Contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at:

<http://ais.nci.nih.gov/forms/Suitability-roster.xls>

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information

Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

Contractor/Subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

d. Information Security Training

HHS policy requires Contractors/Subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (<http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>). This document provides information about information security training that may be useful to potential offerors.

e. Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

f. NIST SP 800 53 Self Assessment

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment required by NIST Draft SP 800-53, Recommended Security Controls for Federal Information Systems. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

g. Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800 18, Guide to Developing Security Plans for Federal Information Systems (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

h. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

i. References

1. Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>

The following NIST publications may be found at the following site: <http://csrc.nist.gov/publications/>

[Note: The search tool on the left side of this page provides easy access to the documents.]

4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

4. Additional Technical Proposal Information

- a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the projects objectives.

- b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

5. Uniform Pricing Assumptions

Contractor proposed budgets should be prepared using the following uniform pricing assumptions:

- a. Task I- Patient Registration, Protocol Patient Data Capture and Quality Control Review System for Phase 0, Phase 1 and Selected Phase 2 Clinical Trials:
 - 25 protocols abstracted per year
 - 60 institutions/performance sites submit data on a biweekly basis
 - 1,000 new patients per year for active protocols
 - Maintenance of a data base of approximately 30,000 patient cases
 - Monthly and ad hoc canned reports as described in the Statement of Work
 - Three training sessions held per year, equipment required for each trainee
 - Programming support and system analysis for new initiatives, including integration and harmonization with the CTEP Enterprise System (AdEERS, CDUS), with emphasis on caBIG™ initiatives, including but not limited to: the common data elements established by the Cancer Data Standards Repository (caDSR), the Enterprise Vocabulary System developed by NCI, Biomedical Research Integrated Domain Group (BRIDG), Clinical Data Interchange Standards and Health Level 7 (HL7) for data transfer. The offeror should discuss the possibility for adoption of a remote data capture system (Clinical Data Management System (CDMS)) to be purchased by NCI and how CDMS could best be incorporated to meet the requirements for Task 1 of the Statement of Work.
- b. Option A - Clinical Data Management System (CDMS) Integration and Maintenance:
 - Assume integration of CDMS will last two (2) years with the remaining five (5) years to perform maintenance.
- c. Task II-Auditing for Phase 0, Phase 1 and Selected Phase 2 Clinical Trials:
 - Assume 70 site visits conducted per year either by a Physician Monitor or a Clinical Research Coordinator or a Clinical Research Associate. Assume that audits are evenly distributed throughout the United States (Note: 3-5 audits per year may include international sites in Canada, Europe or Australia).
- d. Task III- Co-site Visit Monitoring of NCI Clinical Trials Cooperative Groups, Community Clinical Oncology Program (CCOP) Research Bases, Clinical Trials Support Unit (CTSU) and Selected Multi-Institutional Consortia with Quality Assurance Programs:
 - Assume 80 co-site visits conducted per year. Assume that the audits are evenly distributed throughout the United States.
- e. Task IV- Auditing of Investigators Conducting Clinical Trials Sponsored by DCTD at Cancer Centers and Single Institutions:
 - 35 audits conducted per year. Assume that the audits are evenly distributed throughout the United States.
 - Assume the services of outside physicians will be utilized for 10 audits (consulting fees = \$4,000 for all physicians).

f. Option B: Expanded On-Site Auditing Capability:

- Assume additional audits are in increments of 5 above a base of 35 audits per year.

g. Task V- Quality Assurance Program Support for International Group/Institution Collaborators

- Assume 2 training sessions conducted as needed in London, England.

h. Travel: Estimated Cost for the First Year

- Task 1: \$2,000
- Task 2: \$103,000
- Task 3: \$65,000
- Task 4: \$115,000
- Task 5: \$15,000

Budgets for travel for Optional Years 02 through Years 07 will be increased in accordance with negotiated escalation factors.

c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. Cost and Pricing Data

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of offeror;
3. Name and telephone number of point of contact;
4. Name of contract administration office (if available);
5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
6. Proposed cost; profit or fee; and total;
7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property. See Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.;
8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation;

whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;

9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15.2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
 10. Date of submission; and
 11. Name, title and signature of authorized representative.
- B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
 - C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including
 1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
 2. The nature and amount of any contingencies included in the proposed price.
 - D. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
 - E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
 - F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
 - G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
 - H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all

items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403 4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

1. *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403 4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).
 2. *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403 4 and not otherwise exempt, in accordance with FAR 15.403 1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$11.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.
- B. **Direct Labor.** Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:

1. Name and address of licensor.

2. Date of license agreement.
3. Patent numbers.
4. Patent application serial numbers, or other basis on which the royalty is payable.
5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
6. Percentage or dollar rate of royalty per unit.
7. Unit price of contract item.
8. Number of units.
9. Total dollar amount of royalties.
10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205 37).

F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. **General Information**

- a. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
- b. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

3. **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]**

(a) *Exceptions from cost or pricing data.*

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent

necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15.2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406.2.

(End of provision)

Alternate I (October 1997) of FAR Clause **52.215-20, Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** (October 1997). As prescribed in 15.408(I), **substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:**

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

4. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance

with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
 1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
 4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
 1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to

Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$550,000 adopt a plan similar to the plan agreed upon by the offeror.
10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

39.9% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

5. HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

6. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

7. Other Administrative Data

a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

3. Government-Furnished Property

A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at: http://www.hhs.gov/oamp/policies/contractors_guide_for_control_of_gov_property.pdf

b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).*
- (2) The offeror's name and remittance address, as stated in the offer.*
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.*
- (4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.*
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).*
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.*
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.*

(End of Provision)

c. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[] Fac Cap Cost of Money (Has) *The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).*

[] Fac Cap Cost of Money (Has Not) ***has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.*

8. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. Performance History

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

9. Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

10. Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

11. Travel Costs/Travel Policy

a. Travel Costs - Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b. Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions and award term option periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the options.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

- | | Weight |
|---|------------|
| a. Awareness of the Project's Needs; Approach to the Performance of the Tasks | 25% |
| 1. Appropriateness of approaches to data management including upgrades and maintenance to the system for on-line patient registration data; patient data receipt via remote data entry; data processing, data reporting and data clarifications; and, Web based monthly reports and a short turn-around time for requested reports. | |
| 2. Appropriateness of approaches to data security. | |
| 3. Appropriateness of approaches to continued synchronization and integration with designated software data sets, including compatibility with the Clinical Data Update System (CDUS) to permit data transfer from CTMS to CDUS. | |
| 4. Technical approach to achieve the objective of further harmonization and compatibility of CTMS/CTEP databases with caBIG™ or other designated upgrades, particularly with the Clinical Data Update System (CDUS), AdEERS and other databases. | |
| 5. Approach for performing Task II, Task III, Task IV, and Task V: the onsite auditing system for all other investigational clinical trials sponsored by DCTD or select other NCI Divisions. | |
| 6. Knowledge of the FDA regulations, Good Clinical Practices (GCPs), and the International Conference on Harmonization (ICH) standards and their application and impact with domestic institutions as well as international collaborations. | |

7. Appropriateness of plans for cross-training and replacement of proposed staff throughout the course of the contract, including back-up and fill-in personnel.
8. Demonstration of a transition plan that would support a smooth transfer of responsibility from the incumbent Contractor.

- | | |
|--|---------------|
| | Weight
45% |
| b. Personnel and Experience | |
| <ol style="list-style-type: none"> 1. Availability, training and qualifications (e.g., education, training and experience) of a Principal Investigator with specific expertise in the field of oncology and a history of assuming a leadership role. 2. Suitability and adequacy of the training, experience and qualifications of other key personnel (Project Manager, Clinical Research Coordinator(s) and Head, Data Management) and additional personnel. 3. Documentation and demonstration of experience with on-site auditing of oncologic investigational agent studies; experience with FDA, Good Clinical Practices (GCP), NIH and HHS regulations and familiarity with policies and procedures concerning investigational agent trials; and, the mechanics of conducting on-site audits, including chart reviews, pharmacy reviews, pharmacy inspections and regulatory document reviews. 4. Documentation and demonstration of experience with Web based systems, systems for database security, and systems integration utilizing multiple software venues and computerized remote data entry, and data storage, maintenance and retrieval. 5. Demonstration of knowledge and experience for project oversight within offeror's organization as well as coordination with other designated contractors. | |

- | | |
|---|---------------|
| | Weight
20% |
| c. Organizational Experience and Capabilities | |
| <ol style="list-style-type: none"> 1. Documentation and demonstration of the quality of the organization's experience in the management of clinical research trial data and the quality assurance and control of clinical data. 2. Documentation and demonstration of the quality of experience in providing broad quality assurance and auditing and data management tasks identified in the Statement of Work. 3. Approach to providing corporate support to Project Management. 4. Stability of the workforce and ability to recruit and retain staff. | |

- | | |
|--|---------------|
| | Weight
10% |
| d. Facilities and Equipment (Contractor Site) | |
| <ol style="list-style-type: none"> 1. Availability of computers, printers and software possessing Internet capability to access a diverse number of databases. Documentation of availability and overall suitability of facilities and equipment in particular to manage a large database (computer hardware and software, etc). 2. Adequacy of security arrangements for protecting the confidentiality of the records. 3. Adequacy of storage space and the facilities for housing personnel. 4. Adequacy of security and location of the remote facility. | |

4. PAST PERFORMANCE FACTOR

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- a. Extent to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns
- c. Complexity and variety of the work SDB concerns are to perform
- d. Realism of the proposal
- e. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- f. Extent of participation of SDB concerns in terms of the value of the total acquisition.